



## MO HealthNet PA Criteria

Medical Procedure Class:	<b>Insulin Pump, E0784RR</b>
Implementation Date:	<b>08/13/2009 Demo to State 08/14/2009 Smart PA implementation 08/18/2009 CyberAccess implementation</b>
Prepared for:	<b>MO HealthNet</b>
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☒ **New Criteria**

☐ **Revision of Existing Criteria**

### Executive Summary

<b>Purpose:</b>	To allow a consistent and streamlined authorization process for insulin pumps.	
<b>Why was this Issue Selected:</b>	Senate Bill 577 passed by the 94 <sup>th</sup> General Assembly directs MO HealthNet to utilize an electronic web-based system to authorize Durable Medical Equipment using best medical evidence and care and treatment guidelines, consistent with national standards to verify medical need.	
<b>Procedures subject to Pre-Certification</b>	E0784RR: External ambulatory infusion pump, insulin.	
<b>Setting &amp; Population:</b>	All MO HealthNet fee-for-service participants	
<b>Data Sources:</b>	<input checked="" type="checkbox"/> <b>Medicare LCD</b>	<input checked="" type="checkbox"/> <b>MHN Policy</b>

### Setting & Population

All MO HealthNet fee for service participants.

## Approval Criteria

An ambulatory infusion pump for the administration of continuous subcutaneous insulin for the treatment of diabetes mellitus may be covered for patients with a diagnosis of diabetes mellitus. In addition, patients ages 17 and over must meet criterion A or B and criterion C or D; patients under age 17 must meet criterion C or D.

- A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
  - 1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
  - 2. For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory's measurement method.
  - 3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.
- B. Beta cell autoantibody test is positive.
- C. The patient has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:
  - 1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
  - 2. History of recurring hypoglycemia
  - 3. Wide fluctuations in blood glucose before mealtime
  - 4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
  - 5. History of severe glycemic excursions
- D. The patient has been on an external insulin infusion pump prior to enrollment in MO HealthNet and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to MO HealthNet enrollment.

Continued coverage of an external insulin pump requires that the patient be seen and evaluated by the treating physician at least every 6 months. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a physician who manages multiple patients on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

## Denial Criteria

The approval criteria are not met.

## Quantity Limitation

Physician specified length of need up to 12 months rental. (After total rental reimbursements equal \$ 5010.84 the pump will be considered purchased.)

## Conversion

Existing Prior Authorization's will be entered into Smart PA.

## Approval Period

Physician specified length of need up to 12 months.

## Appendix A: Potential Questions for Step 1 and Step 2

**\*\*The following questions may be encountered as part of the approval and denial criteria. Depending on the patient's history and the way previous questions may be answered, not every question may be asked for every patient.**

1. Does the prescribing and requesting physician manage multiple patients on continuous subcutaneous insulin infusion therapy?
2. Does the prescribing and requesting physician work closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy?
3. Is the patient followed by the appropriate disciplinary team?
4. Will the patient be seen and evaluated by the prescribing physician at least every 6 months?
5. Was a C-peptide test obtained?
6. Is the C-peptide level less than or equal to 110% of the lower limit of normal of the lab's measurement method?
7. Does the patient have renal insufficiency?
8. What is the patient's creatinine clearance (actual or calculated from age, weight, and serum creatinine)? \_\_\_ ml per minute
9. Is the fasting C-peptide level less than or equal to 200% of the lower limit of normal of the laboratory's measurement method?
10. Was a fasting blood sugar obtained at the same time as the C-peptide level?
11. What is the fasting blood sugar level? \_\_\_mg/dl

12. Does the patient have a positive beta cell autoantibody test?
13. Has the patient completed a comprehensive diabetes education program?
14. Does the medical record document the patient has been on a program of multiple daily insulin injections of at least 3 per day for at least 6 months prior to initiation of the insulin pump?
15. Does the medical record document frequent self-adjustments of the insulin dose during the past 6 months?
16. Does the medical record document a frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump?
17. What is the patient's glycosylated hemoglobin level (HbA1C)? \_\_\_\_%
18. Does the patient have a history of recurring hypoglycemia?
19. Does the patient have wide fluctuations in blood glucose before mealtime?
20. Does the patient have Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL?
21. Does patient have a history of severe glycemic excursions?
22. Has the patient been on an external insulin infusion pump prior to enrollment with MO HealthNet?
23. Does the medical record document a frequency of glucose self-testing an average of 4 times per day during the month prior to enrollment with MO HealthNet?
24. Is there a written signed and dated physician's order for an insulin pump?
25. Do you hereby certify this item is medically necessary?